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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,268	02/15/2002	Harel Itzhaky	KEINAN=3	3545

1444 7590 09/16/2003

BROWDY AND NEIMARK, P.L.L.C.  
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SUITE 300  
WASHINGTON, DC 20001-5303

EXAMINER
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PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/16/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/914,268

Applicant(s)

ITZHAKY ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

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**DETAILED ACTION**

The preliminary amendment filed February 15, 2002, has been received and entered.

Claims 1-32 are pending and are examined on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-32 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "consisting of or comprising" in claims 1 and 16 renders those claims and their dependents indefinite. Specifically, the claims are indefinite because of their simultaneous use of two transitional phrases having different meanings. It is suggested applicant amend the claim to simply state "a sample suspected of comprising such explosive".

Claim 32 is indefinite because of the recitation "small open receptacles". Specifically, it is not clear how small, or large, the receptacles must be to be encompassed, or excluded,

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from the claim. Because the claim fails to set clear ascertainable metes and bounds a holding of indefiniteness is required. Note that deleting the term "small" would overcome this ground of rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weavers et al (U.S. Pat. 5,736,353) in view of Woiszwillo (U.S. Pat. 5,006,461).

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Weavers discloses ELISA assay processes using a reagent comprising a peroxidase, which may be horseradish peroxidase, and a buffer, said buffer system containing organic solvents including citric acid and surfactants. See column 1, line 61 through column 2, line 41. The disclosed ELISA procedures also use a second reagent comprising a color-producing agent, which may be TMB dissolved in the organic solvent DMSO, and a peroxide substrate. See column 2, line 54 through column 3, line 18. Weavers also discloses that the reagents may combined into kit form. See column 3, lines 19-24.

Weavers differs from applicant's claims in failing to include a solution of a strong acid in the kit. However, Woiszwillo discloses that one method of stopping the peroxidase-catalyzed color reaction in TMB-based peroxidase assays is to add a strong acid, such as the claimed sulfuric. See column 3, lines 3-6. Thus, the artisan of ordinary skill preparing the kit of Weavers clearly would have recognized the desirability of including a solution of strong acid, thereby providing a suitable means of stopping the peroxidase reaction, as disclosed by Woiszwillo. By including an aqueous solution of strong acid in the kit of Weavers, the artisan of ordinary skill would have ensured that all of the reagents required for performing a

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peroxidase-catalyzed TMB-based assay, including the acid stopping reagent, were packaged in a single convenient package.

Lastly, applicant's claimed arrangements of packaging, such as reagent groupings and the use of a plurality of ampoules, clearly would have been a matter of design choice on the part of the artisan of ordinary skill assembling kits for practicing assays such as those disclosed by Weavers or Woiszwilllo. Therefore, absent some demonstration of unexpected result coming from the claimed packaging arrangements, a holding of obviousness is required.

No claims are allowed. However, claims 1-19 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

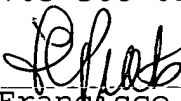
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can

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be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP